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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,564	11/26/2003	Wayne Edward Beimesch	414130	9670

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EXAMINER

ROGERS, DAVID A

ART UNIT PAPER NUMBER

2856

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/724,564

Applicant(s)

BEIMESCH, WAYNE EDWARD

Examiner

David A. Rogers

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 23-34 are rejected under 35 U.S.C. 102(b) as being anticipated by United States Patent 4,930,906 to Hemphill.

Claims 23-31 recite two elements that form the kit, namely an enclosed bag that is sealable to produce a headspace and a list of instructions for how to use the sealable bag. In this regard Hemphill teaches an enclosed bag (reference item 10) and having instructions (reference items 18 and 20). The enclosed bag also has a maximum fill line (reference item 19). This bag, when sealed, would have a headspace above the maximum fill line. In claims 32-34 the applicant's bag is further limited to having an inner aluminum layer and an outer polymeric layer. As seen in figure 5 the bag of Hemphill comprises an aluminum inner layer (reference item 13) and a polymeric intermediate layer (reference item 11). The intermediate layer is disposed on the outside of the inner aluminum layer thus it is an "outside" layer. Furthermore, the applicant's claims use the open-ended term "comprising" thus allowing for any number of layers to be disposed on the polymeric layer. Therefore, Hemphill

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teaches a kit that meets the structural limitations of the applicant's claims. Hemphill does not teach specific instructions with regard to sampling and analyzing.

In the precedential decision *In re Ngai*, 70 USPQ 2d 1862, the Court of Appeals for the Federal Circuit (CAFC) reviewed a situation clearly analogous to the applicant's claims. In *Ngai et al.* a kit was claimed as follows (emphasis added):

19. A kit for normalizing and amplifying an RNA population, said kit comprising instructions describing the method of claim 1 and a premeasured portion of a reagent selected from the group consisting of: oligo dT biotinylated primer, T7 RNA polymerase, annealed biotinylated primers, streptavidin beads, polyadenyl transferase, reverse transcriptase, Rnase H, DNA pol I, buffers and nucleotides.

The CAFC analyzed *Ngai et al.*'s claim 19 and determined that the elements that formed the kit included a premeasured portion of reagent and instructions on how to use the reagent. The cited prior art was a kit having a 10X buffer and specific instructions on how to use the 10X buffer. In referring to *In re Gulack*, 703 F.2d 1381 [217 USPQ 401] (Fed. Cir. 1983), the CAFC stated:

"This case [*Ngai*], however, is dissimilar from *Gulack*. There the printed matter and the circularity of the band were interrelated, so as to produce a new product useful for "educational and recreational mathematical" purposes. Here, addition of a new set of instructions into a known kit does not interrelate with the kit in the same way as the numbers interrelated with the band. In *Gulack*, the printed matter would not achieve its educational purposes without the band, and the band without the printed matter would similarly be unable to produce the desired result. Here, the printed matter in no way depends on the kit, and the kit does not depend on the printed matter. All that the printed matter does is teach a new use for an existing product. As the *Gulack* court pointed out, "[w]here the printed matter is not functionally related to the substrate, the printed matter will not distinguish the invention from the prior art in terms of patentability." *Id.* If we were to adopt *Ngai*'s position, anyone could continue patenting a product indefinitely provided that they add a new instruction sheet to the product."

The CAFC affirmed the Board of Patent Appeals and Interferences (BPAI) and concluded that *Ngai et al.*'s claimed kit was anticipated by the prior art

(the 10X buffer with instructions), despite the fact that Ngai *et al.*'s claim 1 method was distinct from the instructions in the prior art. In fact, the method of claim 1 was determined to be patentable over the prior art. The CAFC further concluded that Ngai *et al.*'s instructions merely taught how to use the reagent component of the kit (the 10X buffer). Specifically, the CAFC concluded:

"All that the printed matter does is teach a new use for an existing product."

and

"He [Nga] is not, however, entitled to patent a known product by simply attaching a set of instructions to that product."

In the present application the instructions merely teach a different use for a known sealable bag. The applicant's claimed enclosed bag does not depend on the claimed instructions in order to function; i.e., the instructions do not enable the bag to hold a sample. Likewise, the claimed instructions do not depend on the bag in order to instruct someone how to sample. Therefore, the applicant's instructions do not enable any sealable bag from holding any material and only describe a process to store a sample in the bag and then to sample the headspace of the bag.

The applicant's claims for a kit comprising a bag and instructions to use the bag is clearly analogous to Ngai *et al.*'s kit having a known reagent (the 10X buffer) and instructions that taught how to use the reagent. The applicant's arguments with regard to how their instructions are not taught by the prior art, and, therefore, there can be no anticipation are also similar to those proffered

by Ngai *et al.* However, both the BPAI and the CAFC unequivocally and unambiguously disagreed with that argument.

Based on the fact that the applicant's kit is known in the art as evidenced by Hemphill, and further because of the CAFC's decision in *In re Ngai*, the applicant's claimed kit is clearly anticipated under 35 USC 102(b).

Furthermore, the intended use of claims 23-34; e.g., for measuring the volatile organic compounds of a material produced in a (spray bed dryer (claims 23, 26, 29), fluid bed dryer (claims 24, 27, 30), storage tank (claims 25, 28, 31)), is not being afforded any patentable weight. The intended use of the kit does not patentably distinguish the applicant's claims over the prior art. As the applicant is fully aware a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the present application the prior art bags are fully capable of holding materials from a fluid bed dryer, a spray bed dryer, or a storage tank.

Response to Arguments

3. Applicant's arguments filed 22 December 2006 have been fully considered but they are not persuasive.

The applicant argues that Hemphill is non-analogous art. However, as the applicant is aware, MPEP §2131.05 states:

“Arguments that the alleged anticipatory prior art is ‘nonanalogous art’ or ‘teaches away from the invention’ or is not recognized as solving the problem solved by the claimed invention, [are] not ‘germane’ to a rejection under section 102.” *Twin Disc, Inc. v. United States*, 231 USPQ 417, 424 (Cl. Ct. 1986) (quoting *In re Self*, 671 F.2d 1344, 213 USPQ 1, 7 (CCPA 1982)). See also *State Contracting & Eng’ g Corp. v. Condotte America, Inc.*, 346 F.3d 1057, 1068, 68 USPQ2d 1481, 1488 (Fed. Cir. 2003) (The question of whether a reference is analogous art is not relevant to whether that reference anticipates. A reference may be directed to an entirely different problem than the one addressed by the inventor, or may be from an entirely different field of endeavor than that of the claimed invention, yet the reference is still anticipatory if it explicitly or inherently discloses every limitation recited in the claims.).

The applicant’s claims are anticipated by the prior art under 35 U.S.C. 102(b) as clearly explained above. Per the CAFC the written instruction do not distinguish the applicant’s claims over the prior art.

Conclusion

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

“Manual for the Certification of Laboratories Analyzing Drinking Water - EPA 815-B-97-001” to the EPA teaches that certified sampling processes require the need for instructions with a kit used for sampling of VOCs. On page IV-3, §5 it is stated:

“All procedural steps in these methods are considered requirements”

Furthermore, §6 states:

“The manner in which samples are collected and handled is critical to obtaining valid data. It is important that a written sampling protocol with specific sampling instructions be available to and used by sample collectors and available for inspection by the certification officer.”

and

"The sample collector should be trained in sampling procedures and have complete written sampling instructions (SOPs) for each type of sample to be collected."

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

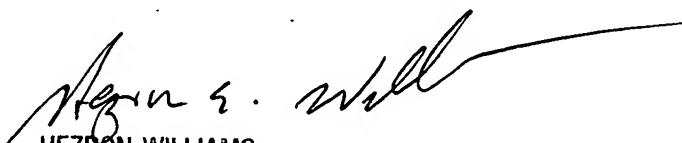
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Rogers whose telephone number is (571) 272-2205. The examiner can normally be reached on Monday - Friday (0730 - 1600). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Hezron E. Williams can be reached on (571) 272-2208. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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7. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

darr

18 January 2007


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